

# ZOLON F.C. TABLETS

Zopiclone (7.5mg)

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## What Zolon F.C. Tablets is used for

Zolon Tablet is used to help adults with trouble sleeping, whether it is temporary, short-term, or long-lasting. It is used to help with difficulty falling asleep, waking up in the middle of the night, or waking up too early.

## How Zolon F.C. Tablets works

The active ingredient of this medicine is zopiclone. Zopiclone is an hypnotic and sedative agent. It works by increasing the effects of a natural chemical in your brain called GABA, which slows down brain activity. This makes you feel relaxed and sleepy, helping you fall asleep faster and stay asleep longer.

## Before you take Zolon F.C. Tablets

### - When you must not take it

Do not take Zolon F.C. Tablets if you:

- are hypersensitive to zopiclone, or any other ingredients of this medicine (listed in Product Description).
- have severe liver problems.
- have serious breathing problems (respiratory failure).
- have severe sleep apnoea (a condition where breathing stops and starts during sleep).
- suffer from myasthenia gravis (a disease which causes severe muscle weakness).

Zolon F.C. Tablets is not to be used in children.

### - Before you start to take it

Check with your doctor if you have:

- kidney or liver problems.
- depression or certain personality disorders.
- a history of alcohol or drug abuse.

### *Pregnancy and Lactation*

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using this medicine.

Do not take Zolon F.C. Tablets if you are pregnant, as it may potentially cause harm to your baby.

Zolon F.C. Tablets is secreted into the breastmilk, therefore, breastfeeding is not recommended while taking this medicine.

### - Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket, or health food shop.

Tell your doctor or pharmacist if you are taking:-

- Antipsychotics medications (for mental health conditions).
- Sleeping pills or other hypnotics medications.
- Anxiety medications.
- Certain antidepressants.
- Strong painkillers (narcotics).
- Sedating antihistamines (for allergies).
- Antibiotic such as erythromycin and clarithromycin.
- Medicines to treat fungal infections such as ketoconazole, itraconazole.
- Rifampicin, medicines used to treat HIV infections.
- Seizure medications, such as phenytoin, phenobarbital and carbamazepine.
- St John's Wort (a herbal supplement for mood).

If you are going to undergo any procedure or surgery that requires anaesthesia, please inform your doctor or nurse that you are taking Zolon F.C. Tablets.

## How to take Zolon F.C. Tablets

### - How much to take

Adults:

Take 1 tablet by mouth before bedtime. Do not take more than the dose prescribed.

Elderly:

Your doctor will start with a lower dose (half tablet).

Children:

Not recommended.

Individuals with liver problems:

Your doctor will start with half (1/2) tablet; and if needed, the dose may be increased to 1 tablet with caution.

### - When to take it

Take once daily or as directed by your doctor or pharmacist.

### - How long to take it

Take this medicine for the duration that your doctor recommends.

### - If you forget to take it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose

### - If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause drowsiness, confusion, extreme tiredness. In more serious cases, a person may experience loss of balance, weak muscles, low blood pressure, trouble breathing, or even fall into a coma.

## While you are taking it

### - Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are using Zolon F.C. Tablets.
- Tell your doctor immediately if you become pregnant while taking this medication.
- Take Zolon F.C. Tablets only with a doctor's prescription.

### - Things you must not do

- Do not take any new medicines without consulting your doctor.
- Do not give Zolon F.C. Tablets to anyone else, even if they have the same symptoms or condition as you.

### - Things to be careful of

#### *Driving and using machines*

This medicine may affect your ability to drive or use machines. If the tablets cause nausea, dizziness, headache or drowsiness, do not drive or use machines and contact your doctor immediately.

Zopiclone can affect alertness and coordination, making activities like driving or operating machines dangerous. The risk of slower reaction and impaired judgement is higher if it is taken within 12 hours of these activities, especially if more than the recommended dose is taken, or if combined with alcohol or other sedating medicines. To stay safe, avoid tasks that require full concentration for at least 12 hours after taking zopiclone.

Do not use longer than 4 weeks, unless instructed by your doctor. Long-term use may reduce effectiveness (tolerance) and increase withdrawal effects.

Rebound insomnia: Stopping suddenly may worsen sleep problems, anxiety, or mood changes. It is better to reduce the dose gradually.

Memory issues (amnesia): Rarely, memory loss can occur, especially if you wake up too soon after taking it. Ensure you get a full night's sleep.

Unusual sleep behaviors: Some people may sleepwalk, eat, or even drive in their sleep without remembering it. If this happens, stop taking the medication and consult your doctor.

### Side Effects

Like all medicines, Zolon F.C. Tablets can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you experience any side effects after taking Zolon F.C. Tablets including:-

Most common

- bitter or metallic taste around mouth.

Less common

Mild gastrointestinal disturbances:

- nausea and vomiting
- dizziness
- headache
- drowsiness
- dry mouth

Rare side effects

Psychological and behavioural disturbances (most likely to occur in the elderly)

- irritability
- aggressive
- confusion
- depression
- memory problems (anterograde amnesia)
- hallucination
- nightmare

Allergic

- hives or rashes

Very rare side effects

- light headedness
- impaired coordination
- Severe facial swelling (angioedema)
- Severe allergic reactions (anaphylaxis)
- Mild to moderate increase in liver enzymes (serum transaminases, alkaline phosphatase)

Other side effects:

Withdrawal symptoms (if stopped suddenly):

- rebound insomnia (worsen sleep problems)
- anxiety, tremors, sweating, agitation
- confusion, headaches, rapid heartbeat (palpitations, tachycardia)
- delirium, panic attacks, nightmares, hallucinations
- muscle aches, cramps, stomach issues
- seizures (very rare)

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### Storage and disposal of Zolon F.C. Tablets

#### - Storage

Store at temperature below 30°C. Protect from light.

#### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### Product Description

#### - What it looks like

It is a white, oval biconvex film-coated tablet, with "S||T" scored on one side and a "404" score on the other side.

#### - Ingredient(s)

- Active Ingredient
- Zopiclone

- Inactive Ingredients

- Talc
- Titanium Dioxide
- Polyethylene Glycol 6000
- Magnesium Stearate
- Lactose
- Povidone
- Hydroxypropyl Methyl Cellulose
- Purified Water
- Alcohol 95%

#### - MAL number

MAL09020983AZ

#### **Manufacturer**

Taiwan Biotech Co.,Ltd  
22, Chieh-Shou Road,  
Taoyuan, Taiwan, R.O.C

#### **Product Registration Holder**

Sunward Pharmaceutical Sdn. Bhd.  
No. 9,11 & 17, Jalan Kempas 4,  
Taman Perindustrian Tampoi Indah,  
81200 Johor Bahru, Johor, Malaysia.

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21/07/2025

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